IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

TELADOC, INC., TELADOC PHYSICIANS, P.A., KYON HOOD, AND EMMETTE A. CLARK PLAINTIFFS, V. TEXAS MEDICAL BOARD, MICHAEL ARAMBULA, JULIE K. ATTEBURY, MANUEL G. GUAJARDO, JOHN R. GUERRA, J. SCOTT HOLLIDAY, MARGARET C. MCNEESE, ALLAN N. SHULKIN, ROBERT B. SIMONSON, WYNNE M. SNOOTS, PAULETTE B. SOUTHARD, KARL W. SWANN, SURENDA K. VARMA, STANLEY S. WANG, AND GEORGE WILLEFORD III, individually and in their capacities as members of the Texas Medical Board, DEFENDANTS.	CIVIL ACTION NO. 1:15-CV-00343-RP JURY TRIAL DEMANDED

BRIEF OF FEDERATION OF STATE MEDICAL BOARDS AS AMICUS CURIAE IN OPPOSITION TO PLAINTIFFS' APPLICATION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

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INTEREST OF AMICUS CURIAE

This case is a challenge by Teladoc and related plaintiffs to 22 Tex. Admin. Code § 190.8(1)(L). In essence, that regulation requires that, before prescribing "any dangerous drug or controlled substance" to a patient in Texas, a physician must first have established a defined physician-patient relationship. Under the regulation, establishing such a relationship requires that the physician examine the patient either in person or by electronic means with a health care professional present with the patient if the physician is at a remote site, including the patient's home. Notably, plaintiffs are not challenging the Texas telemedicine statute or any of the existing telemedicine regulations in 22 Tex. Admin. Code § 174. Rather, the sole question before this Court is whether the Texas Medical Board violated the federal antitrust laws or the commerce clause in requiring that a physician see a patient, either in person or by some form of video, before prescribing potentially dangerous or addictive pharmaceuticals.

The Federation of State Medical Boards has a direct interest in this question. The purposes of the Federation include supporting the ability of State Boards of Medicine to issue regulations and take other actions that such Boards reasonably believe to be in the best interests of patients and patient safety. The Federation believes that that is what the Medical Board did in this case. Specifically, after notice and comment rule-making in accordance with the Texas Administrative Procedure Act, the Board concluded that, given the risks posed by the prescription of dangerous drugs and controlled substances, both the safety of the patient and the need to minimize diversion and other misuse of these pharmaceuticals require that the physician examine the patient either in person or by acceptable electronic means. The Federation will explain in this memorandum why we believe that this regulatory action is fully consistent with applicable law.

The Federation of State Medical Boards is a national non-profit organization whose members are the seventy (70) state medical licensing and disciplinary boards of the U.S. and its

Territories. Since 1912, our mission has been to improve the quality, safety, and integrity of health care by promoting high standards for physician licensure and practice and to support State Medical Boards in protecting the public. Moreover, the Federation is uniquely positioned to provide this Court with information about the development of rules and regulations addressing telemedicine and about the role of regulatory agencies in protecting public safety.

We first issued "Model Guidelines for the Appropriate Use of the Internet in Medical Practice" in 2002. Since then, we have offered recommendations to State Medical and Osteopathic boards seeking to establish the appropriate balance between enabling access to care through telemedicine while ensuring patient safety. In 2014, we released the Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine. Among its key provisions, this report states that the same standards of care that have historically protected patients during in-person medical encounters must apply to medical care delivered electronically. Care providers using telemedicine must establish a credible "patient-physician relationship," ensuring that patients are properly evaluated and treated and that providers adhere to well-established principles guiding privacy and security of personal health information, informed consent, safe prescribing and other key areas of medical practice.

The decision of this Court will directly impact the ability of the Texas Medical Board to protect patients and the public from prescription of dangerous drugs and controlled substances without adequate physician examination. More generally, it is likely to have a significant impact on the ability of State Medical and Osteopathic Boards across this country to issue regulations that they determine to advance the State's interest in protecting patients and the public. For these reasons, the Federation of State Medical Boards respectfully submits this amicus brief.

ARGUMENT

To prevail on an application for a preliminary injunction in this Circuit, a movant must make four showings:

1) There is a substantial likelihood that it will prevail on the merits;

2) There is a substantial threat that it will suffer irreparable injury if a preliminary injunction is denied;

3) The threatened injury to the movant outweighs the threatened injury to the party to be enjoined; and

4) Granting the preliminary injunction will not disserve the public interest.

See, e.g., PCI Transp., Inc. v. Fort Worth & Western Railroad Co., 418 F.3d 535, 545 (5th Cir. 2005). Indeed, courts have "cautioned repeatedly" that a preliminary injunction is an "extraordinary remedy" to be granted only if the movant has "clearly carried the burden of persuasion." *Id.*

Accordingly, a movant must establish each of these four elements by a "clear" and "unequivocal" showing. *Evergreen Presbyterian Ministries, Inc. v. Hood*, 235 F.3d 908, 917 (5th Cir. 2000); *Valley v. Rapides Parish School Bd.*, 118 F.3d 1047, 1050 (5th Cir. 1997). *See also, Walgreen Co. v. Hood*, 275 F.3d 475, 477 (5th Cir. 2001) Here, plaintiffs cannot establish any of these elements – let alone all of them by a clear and unequivocal showing.

I. PLAINTIFFS CANNOT ESTABLISH A SIGNIFICANT LIKELIHOOD OF SUCCESS ON THE MERITS.

Plaintiffs have advanced two claims in this litigation. First, they assert that the challenged regulation violates Section 1 of the Sherman Act, 15. U.S.C. Section 1. Second, they argue that the regulation violates the commerce clause of the United States Constitution. They cannot establish a reasonable likelihood of success on either cause of action.

A. The Antitrust Claim.

Plaintiffs' first claim is that the challenged regulation suppresses competition by physicians who practice telemedicine but who do not actually see the patient before prescribing certain pharmaceuticals against physicians who maintain a traditional office-based practice where physicians physically examine a patient and take a medical history before prescribing a controlled substance or other dangerous drug (or physicians who practice telemedicine in accordance with the regulation). In support of this claim, plaintiffs invoke the recent decision of the Supreme Court in *North Carolina State Board of Dental Examiners v. FTC*, __ U.S. __, 135 S.Ct. 1101 (2015).

In that case, the FTC challenged cease-and desist letters written by the North Carolina Dental Board declaring that tooth whitening activities of non-dentists constituted the unlicensed practice of dentistry and could expose the unlicensed practitioners to criminal sanctions. The Board defended on grounds that, as an agency of the State of North Carolina, it is immune from the federal antitrust laws by virtue of the so-called "state action" doctrine. The Supreme Court held, however, that a state agency that is controlled by practitioners in the market that it regulates is protected by the state action doctrine only if it is actively supervised by the State. Notably, the Court did not prescribe what sort of state supervision would immunize a State regulatory Board from antitrust liability. It noted only that the inquiry is "flexible and context specific." *Id.* at 1116.

Plaintiffs here cannot show a reasonable likelihood of success on their antitrust claims for two reasons. First, unlike the actions of the North Carolina Dental Board, the regulation before this Court is actively supervised by the State. Second, even if the regulation were subject to the antitrust laws, it does not suppress competition.

1. Implementation Of The Challenged Regulation Is Actively Supervised By The Texas Courts And Is Therefore Immune From The Federal Antitrust Laws.

The challenged regulation is immune from the federal antitrust laws because, unlike the cease-and-desist letters in *North Carolina State Board of Dental Examiners*, it is subject to judicial review to determine whether it comports with the policy of the State. To be sure, the Supreme Court has never squarely decided whether judicial review of a regulation of a state agency constitutes "active state supervision" for purposes of the state action doctrine. However, it has strongly indicated that "state courts, acting in their judicial capacity, can adequately supervise private conduct for purposes of the state action doctrine." *Patrick v. Burget*, 486 U.S. 94, 103 (1988). *Patrick* suggests that judicial review will satisfy the "active state supervision" prong of the state action doctrine if it considers whether the conduct in question "accorded with state regulatory policy." *Id*. at 105.

Here, there is little doubt that the regulation is subject to review in the Texas state courts to determine whether it accords with the regulatory policy of this State. Section 2001.038(a) of the Texas Administrative Procedure Act, 10 Texas Government Code, Section 2001.038(a) explicitly provides as follows:

> The validity or applicability of a rule, including an emergency rule adopted under Section 2001.034, may be determined in an action for declaratory judgment if it is alleged that the rule or its threatened application interferes with or impairs, or threatens to interfere with or impair, a legal right or privilege of the plaintiff.

Under this statute, the courts are called upon to determine whether a regulation such as the one at issue here accords with state policy. Thus, in an action brought by plaintiff Teladoc against the Texas Medical Board, the Court of Appeals ruled that, in enacting Section 2001.038, the Legislature has empowered the courts to determine whether "reasoned justification" supports a challenged rule. *Teladoc v. Tex. Med. Board*, 453 S.W.2d 606,623 (2014). It held that the Texas

Medical Board may not "stray" from the "legal limitations" imposed upon it by the Legislature. *Id.* at 622. *See also, Public Util. Comm. v. City Pub. Servs. Bd.*, 53 S.W.2d 310, 316 (Tex. 2001) (A state agency may not exercise a power contradictory to a statute on grounds that such power is expedient for administrative purposes.)

Implementation of the rule challenged in this case is readily distinguishable from the cease-and-desist letters at issue in *North Carolina State Board of Dental Examiners.* In that case, there was no readily available judicial review of the conduct of the State Board, and that Board did not even contend that the challenged conduct was actively supervised by the State. Here, by contrast, there is immediate and substantive review of the rule at issue in the Texas State courts. This judicial review constitutes active state supervision that immunizes the regulation from antitrust scrutiny. Indeed, if it did not, the federal antitrust laws would have replaced the Texas Administrative Procedure Act as the method for judicial review of regulations of state boards comprised of practitioners in the regulated market. Surely, that is not the law. At the very least, there is sufficient doubt about this issue that it cannot be said that plaintiffs have a substantial likelihood of success on their antitrust claim.

2. **The Challenged Regulation Does Not Suppress Competition.**

Even if the regulation were subject to the antitrust laws, there is no substantial likelihood that plaintiffs will be able to prove that the challenged regulation violates the law. Here, it must be reiterated that the regulation does not prohibit telemedicine or impose severe restrictions on telemedicine generally. It simply requires that, before any physician prescribes a dangerous drug or a controlled substance for a patient, that physician must see the patient – whether in person or by electronic means by which a health care professional is with the patient to assist the physician in the remote location in examining the patient. Thus, what is at issue in this case is a challenge to a narrow regulation regarding when a physician may prescribe "any dangerous drug or controlled

substance." 40 Tex. Reg. 1019, Mar. 6, 2015 (proposing amendment to 22 Tex. Admin. Code § 190.8(1)(L)).

The regulation requires the establishment of a "defined physician-patient relationship" before dangerous drugs or controlled substances may be prescribed. *Id*. To establish such a relationship, the physician has to perform a "face-to-face visit or in-person evaluation," which (thanks to how the regulation broadens access to telemedicine) can even include a telemedicine "visit" in the patient's home under appropriate circumstances. *See id.* at 40, Tex. Reg. 1017 (proposing amendment to 22 Tex. Admin. Code 174.6(d)(1), permitting the patient's home to constitute an "established medical site" in certain circumstances); *see also* 22 Tex. Admin. Code 174.2(3) (defining "face-to-face visit" to include an evaluation when the patient is at an "established medical site"). In effect, it places the same sort of requirement on telemedicine practitioners as it does on physicians practicing in an office or hospital setting. Thus, it provides parity in the standards applicable to traditional medical practice and practice through evolving forms of technology.

There can be no doubt that the rule in question, assuming that it is subject to the antitrust laws at all, must be evaluated under the rule of reason. Under that methodology, the purpose of the analysis is to form a judgment about the competitive significance of the restraint. *Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 691-92 (1978). Because the challenged regulation requires all physicians to actually see the patient before prescribing the pharmaceuticals covered by the regulation – regardless of method used to interact with the patient – the regulation cannot be said to suppress competition in any way.

To the contrary, the regulation promotes competition by ensuring that physicians compete to provide patients the care that they need through a requirement that the patient be seen before

potentially dangerous or addictive drugs are prescribed. It does not unfairly disadvantage telemedicine practitioners. Rather, it assures that care provided via telemedicine meets the same standard as care provided in person, *i.e*. that there must be an established patient-physician relationship before any prescriptions are issued for the drugs covered by the rule.

Further evidence that the regulation is designed to protect patients and the public – and that it is not some malevolent effort by self-interested physicians on the Texas Medical Board to suppress competition -- can be found in the fact that numerous states have analogous requirements. In Alaska, for example, "providing treatment, rendering a diagnosis, or prescribing medications based solely on a patient-supplied history that a physician licensed in this state received by telephone, facsimile, or electronic format" is deemed unprofessional conduct unless a licensed health care provider is with the patient. 12 AAC 40.967 (27). Additionally, unprofessional conduct includes "prescribing, dispensing, or furnishing a prescription medication to a person without first conducting a physical examination of that person, unless the licensee has a patient-physician or patient-physician assistant relationship with the person." 12 AAC 40.967 (29).

Similarly, in Arkansas, the standard for a proper physician-patient relationship requires, at a minimum, the physician to perform "a history and physical examination of the patient adequate to establish a diagnosis and identify underlying conditions and/or contraindications to the treatment recommended/provided," or the physician "personally knows the patient and the patient's general health status through an 'ongoing' personal or professional relationship." Code Ark. R. 060.00.1-2. And in Alabama, a provider who provides telehealth medical services at a site other than an established medical site for a patient's previously diagnosed condition must either "see the patient one time in a face-to-face visit before providing telehealth medical care," or "see the patient without an initial face-to-face visit, provided the patient has received an in-person evaluation by another

provider who has referred the patient for additional care, and the referral is documented in the medical record." Ala. Admin. Code 540-X-15-.10.

In short, there are very strong arguments that the challenged regulation is a reasonable measure designed to protect patients from problems that can arise in the prescription of dangerous drugs and controlled substances when the physician has not previously seen the patient. It is also a reasonable measure to help assure that prescribing physicians will actually establish a proper relationship with the patient before prescribing controlled substances that are easily capable of diversion for inappropriate use by patients wishing to sell such substances on the street. Subjecting telemedicine practitioners to similar requirements as those imposed on traditional practitioners in these circumstances cannot properly be deemed anticompetitive. At a minimum, it cannot fairly be said that plaintiffs have a substantial likelihood of success.

B. The Commerce Clause Claim.

Plaintiffs are not likely to succeed on the merits of their dormant Commerce Clause claim either. As an initial matter, the regulation is not facially discriminatory. Nor does it have the effect of burdening only out-of-state physicians. *See, e.g., Pharm. Research & Mfrs. of Am. v. Cnty. of Alameda*, 768 F.3d 1037, 1042 (9th Cir. 2014) ("The Ordinance, both on its face and in effect, applies to all manufacturers that make their drugs available in Alameda County—without respect to the geographic location of the manufacturer."). Indeed, as the press release announcing the regulation makes clear, the rule would affect a patient "in rural north Texas" who sought treatment "via telemedicine by a doctor in Dallas," or a "west Texas patient in an assisted living facility" who was treated via telemedicine "by an Austin psychiatrist." TMB Adopts Rules Expanding Telemedicine Opportunities, Apr. 14, 2015, http://www.tmb.state.tx.us/dl/DAD89645-F81F-CF51-6FF8-D0E20891625A. And, based on Teladoc's own submissions to this Court, it appears that the vast majority of the services provided by Teladoc in Texas is entirely in-state. (Dkt. No. 10 at 23

(explaining that only "16.5% of Teladoc consultations for Texas patients are performed by Texas-licensed physicians located outside the state.").)

Because the regulation would "treat every private business, whether in-state or out-of-state, exactly the same," it does "not discriminate against interstate commerce for purposes of the Commerce Clause." *United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 334 (2007). Even if all telemedicine were provided by out-of-state physicians – which is emphatically not the case – the "across-the-board" regulation would still be non-discriminatory. *See Pharm. Research & Mfrs.*, 768 F.3d at 1042 (holding that a neutral regulation is non-discriminatory "even where the ordinance only affects interstate commerce due to an absence of intrastate businesses"). Under *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970), a neutral rule like § 190.8(1)(L) that "regulates evenhandedly to effectuate a legitimate local public interest" must be "upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." *Id*. at 142.

Plaintiffs cannot meet that standard here. The Supreme Court has explained that "a State's power to regulate commerce is never greater than in matters traditionally of local concern," and regulations that "touch upon safety . . . are those that the Court has been most reluctant to invalidate." *Kassel v. Consol. Freightways Corp.*, 450 U.S. 662, 670 (1981) (internal quotation markets and citations omitted). Here, the Texas Medical Board has proposed a regulation of the practice of medicine—and in particular, a regulation designed to protect the public health and safety when it comes to the prescription of "any dangerous drug or controlled substance." 40 Tex. Reg. 1019 (Mar. 6, 2015). It would take a very significant burden on interstate commerce to justify interfering in the Board's efforts to protect the health and safety of the citizens of Texas, a core matter of local concern. *Cf. Ferndale Labs. Inc. v. Cavendish*, 79 F.3d 488, 495 (6th Cir. 1996)

(rejecting dormant Commerce Clause challenge: "Prescription drugs can be and are abused and unlawfully distributed in Ohio and elsewhere. Ohio's interest in preventing such illegal drug transactions is manifest.").

The only relevant burden that plaintiffs have identified is that the costs of providing telehealth consultations – for in-state and out-of-state providers alike – may increase. (Dkt. No. 10 at 23.) Even if true (which is far from clear), that will not suffice to establish a Commerce Clause violation. And it will certainly not suffice to show that plaintiffs have a substantial likelihood of success.

II. A WEIGHING OF THE EQUITIES TIPS DECIDEDLY AGAINST ISSUANCE OF A PRELIMINARY INJUNCTION.

A. Plaintiffs Will Not Suffer Irreparable Injury If A Preliminary Injunction Is Denied.

The Supreme Court held that a plaintiff seeking a preliminary injunction must always show that irreparable harm is "likely," not merely "possible." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 21-22 (2008). Here, plaintiffs will not suffer any substantial injury if the challenged regulation is implemented while this case is being decided on the merits. As noted above, this regulation is not a ban on telemedicine – or even a severe restriction on the practice of telemedicine generally. It is simply a rule that requires a physician to see the patient before prescribing certain categories of potentially harmful or addictive drugs. It actually broadens the ability of physicians who do not see the patient in person to prescribe such drugs in that it permits an examination by videoconference from the patient's home as long as the patient is accompanied by a qualified health care professional who can assist the remote-site physician with the examination.

If a preliminary injunction is denied and if plaintiffs want their physicians to be able to prescribe the drugs in question, they will simply have to make arrangements to make video equipment available at the patient's residence and to have an appropriate health care professional

present during the remote site examination. Alternatively, plaintiffs can arrange to have the patient brought to a facility that has the necessary equipment and personnel. And they need only do this once – not every time that the physician wishes to prescribe. The regulation does not place any other limitations on the practice of telemedicine by plaintiffs or otherwise interfere with plaintiffs' business. The fact that plaintiffs would prefer not to incur the costs of taking these precautions before its physicians prescribe dangerous drugs or controlled substances is hardly the sort of irreparable injury that would justify a preliminary injunction.

B. The Texas Medical Board Would Suffer Substantial Injury If A Preliminary Injunction Were Granted.

The Texas Medical Board in this case has gone through an extensive rule-making in accordance with the requirements of the Texas Administrative Procedure Act to craft a narrowly tailored rule designed to protect patients and the public from harms associated with prescription of powerful and sometimes addictive pharmaceuticals before the patient is seen by the physician. The process set forth by the Texas Legislature for review of a regulation of this nature is judicial review under the Administrative Procedure Act. In such a procedure, the Medical Board will have the ability in a plenary proceeding to explain the procedure that it followed in issuing the regulation, the reasons that the regulation accords with Texas law and policy, and the medical considerations that underlie the regulation. However, issuance of a preliminary injunction by this Court under the federal antitrust laws or the commerce clause would essentially preempt such judicial review and would deprive the Board of its ability to explain, in the manner determined by the Legislature, the lawfulness of the regulation that it issued – a regulation that subjects not just plaintiffs, but all physicians licensed in Texas to the same standard of care.

III. THE PUBLIC INTEREST STRONGLY SUPPORTS DENIAL OF A PRELIMINARY INJUNCTION.

The Texas Medical Board is the "the primary means of licensing, regulating, and disciplining physicians" in Texas. Tex. Occ. Code § 151.003(2). In furtherance of this role, the Board is responsible for the promulgation of rules necessary to regulate the practice of medicine within the State. Tex. Occ. Code §153.001 (3). Thus, when the Board issues rules for physicians engaging in the practice of medicine, it is carrying out its duty to ensure that physicians who practice medicine, either through a face-to-face encounter with a patient or through telemedicine, do so in a safe manner. That is what the Board did here.

The Board considered the risks to patients and the public of the prescription of various categories of pharmaceuticals without face-to-face examination of the patient. It concluded that, on balance, a face-to-face examination was necessary before a physician can safely prescribe dangerous drugs or controlled substance. It did not require that the examination be in person. Rather, it allowed telemedicine providers to prescribe the drugs at issue as long as they conduct a video examination of the patient at a remote site, including at the patient's home, provided that a qualified health care professional is present with the patient. It would be diametrically opposed to the public interest to have this Court substitute its judgment, on the basis of the incomplete record that is inevitable at the preliminary injunction stage of litigation, for the considered decision of the agency charged by the Legislature of this State to regulate medicine in the best interests of patients and the public.

Finally, it should be noted that the decision in this case is likely to have a significant impact on efforts by Boards of Medicine in other states to fashion regulations that they believe would serve the interests of patients and the public. A preliminary injunction in this case would send a signal across the United States that a plaintiff who feels aggrieved by a rule designed to advance patient

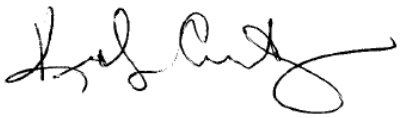
and public safety need only assert a colorable antitrust (or commerce clause) claim – and the considered efforts of the responsible state agency will be struck down on an incomplete record. In this connection, it is worth recalling the following admonition of the Supreme Court in *North Carolina State Board of Dental Examiners*, 135 S. Ct. at 1109: "[I]f every duly enacted state law or policy were required to conform to the mandates of the Sherman Act thus promoting competition at the expense of other values a State may deem fundamental, federal antitrust law would impose an impermissible burden on the State's power to regulate."

It is well settled that the antitrust laws are supposed to be "a consumer welfare prescription." *Reiter v. Sonotone Corp.*, 442 U.S. 330, 343 (1979). A preliminary injunction in this case would be the exact wrong prescription for the people of Texas and across this country. Plaintiffs' application for a preliminary injunction should be denied.

CONCLUSION

For the foregoing reasons and for the reasons set forth in the brief of the Texas Medical Board, this Court should deny the application for a preliminary injunction.

Respectfully submitted on
May 20, 2015:

By: 

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CERTIFICATE OF SERVICE

I certify that, on the 20th day of May 2015, a true and correct copy of the foregoing was forwarded to all counsel of record by electronic service through the Court's CM/ECF system in compliance with the Federal Rules of Civil Procedure.